Panel Discussion

Technology Transfer: Industry's Role in Getting Life Changing Inventions to the People Who Need Them

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I'm honored to have this opportunity to speak to you, because some of the subjects that we were asked to cover are critical to our country's future and pertain to the issue of bringing assistive technologies to the marketplace where they can help people.

The subject I've been asked to talk about is technology transfer, particularly how we can facilitate the translation of these technologies to industry. We also need to figure out the role of industry in getting life-changing inventions to the people who need them. I am going to talk about this very important subject in a way that, hopefully, won't disappoint some of you, because some of my ideas may be rather controversial.

First, let's consider the processes that exist today. Substantial government support is provided to academia for research, and the quality of science created at our elite research universities is extraordinary.

However, not many of these discoveries end up in products. Why this failure? Scientific discoveries create knowledge, not products. Often, the researchers try to speculate how their science can lead to products. They and the technology transfer offices of the universities then try to find partners. All too often, the professors themselves try to get involved and maybe for the wrong reasons. In my opinion, the process prostitutes the role of the university, degrades the potential of the technology, and rarely leads to success.

I believe the process is all wrong, and the results essentially attest to this stance. Although occasional exceptions exist, the professors usually fail to gain their objective and the university often gets very little from the investment.

Indeed, even in the few successes, most of the value goes to others. What's wrong with this scenario? Most importantly, rarely does the academic have any idea what it takes to get a product to market.

I've been asked on numerous occasions to speak on the subject of entrepreneurship. In those talks, I generally list what I consider the 10 most important factors leading to a product's business success. In my list, capital is at the top, at number one, and the product is at the bottom, at number 10.

On occasion, I further consider the factors needed to create a promising product. Here again, the basic idea, the intellectual property itself, is number 10, at the bottom of the list. The entire concept of technology transfer today, in my view, is misguided.

How can we fix this? A number of approaches might improve the odds. Essentially, all of these approaches incubate the idea using an industrial team—not an academic team, but an industrial team—to advance the development to a later stage when far greater value can be realized.

My own approach is derived from what I have observed. The financial markets today have such a short focus that thriving public companies can't really support basic development that won't yield marketable products in a short time, at least in most industries.

Of course, infrequent exceptions do exist, like our colleague over here from Intel, because sometimes you might find a company like Intel developing a new microchip that might take a significant amount of time.

With Wall Street's demands for increasing profits every quarter, what is a public company to do? This is especially a challenge for the larger companies. How does a company with annual revenues of $20 billion increase its revenues and profits by 10 percent or so a year, enough to satisfy the financial world?

The answer, of course, is through acquisitions. Yet these companies are reluctant to acquire early stage ventures with only basic intellectual property. They view the risks as too great, and they worry that the opportunity will get lost in their bureaucracy.

They prefer acquiring new products by buying the companies later in the process, usually after most of the technical risks are resolved. They understand and are willing to accept market risks, but they shy away from the risk in the product itself. They would rather pay a higher price when there is greater certainty of success.

The approach so often employed today is for some new technology to get developed into a product within a startup company. Once the development risk is largely eliminated, the venture is acquired. When this scenario works, everyone usually wins. Often, it fails in an early stage because the initial principals don't adequately understand the opportunity and its limitations.

Too often, the inventors are principals in the venture, and they are imbued with the not-invented-here syndrome. Too often, they fail to see the limitations of their inventions.

The angels, or venture capitalists that fund the efforts, probably don't really understand the market or the technology. The outside management team that is hired simply wants success at any cost, no matter what. As a result, most of these ventures fail, and so the process becomes very expensive.

A number of approaches are being explored that intend to yield a better likelihood of success. One especially pertinent to companies based on technology is to create incubators to carry on the initial development efforts, at least until technical feasibility is established.

By sharing community resources, such as laboratories, expensive equipment, and support infrastructure, the costs are reduced. Yet the basic challenge of prudent product selection is often still not answered, so even these incubator projects often fail.

I've seen one incubator spin off 30 companies over a few years, 25 of which have already failed. If appropriate diligence is utilized in selecting the projects and if adequate resources are applied to both people and capital, a promising plan should evolve.

Years ago, I myself adopted a somewhat different approach. I've been very fortunate. I've started a number of companies, and the first seven companies that I've founded and led have all been successful. I have amassed a significant fortune, and I am trying to give back to society and to my country.

I aim to do this by creating industrial product development organizations on the campuses of elite research universities. I plan to endow a total of at least 12 of these Alfred Mann Institutes over the next few years, devoted entirely to life sciences. Each will be initially endowed with $100 million, but this amount may increase significantly if the institute is well received and is promising.

The institute director and its board of directors will establish the specific areas of interest for each institute. The institute will employ a staff of product development engineers and scientists

recruited from industry with relevant experience, and will establish adequate support infrastructure to move the appropriate intellectual property from the university to a late stage of development.

One AMF project is Second Sight, which has developed a visual prosthesis already implanted in six human patients. The prosthesis provides usable sight to people with retinitis pigmentosa and macular degeneration.

Medical devices developed within the institutes are to be pursued at least through product qualification and often through clinical trials. Pharmaceuticals are generally to be carried at least through Phase II clinical trials. Only then will these later-stage development projects be licensed out to existing or startup ventures. By this time, substantial value will already have been created.

The financial returns to the institute are divided among the parties. The inventor receives a moderate portion of the income and/or the equity, and the institute and the university are rewarded with much larger shares. To be sure, these institutes will probably also pursue projects that are doomed to failure. So, the selection process is critical. Before adopting the institute model, I created the freestanding Alfred Mann Foundation (AMF). I've seen great success from this organization, which now employees 103 engineers and scientists.

At AMF, the projects are usually initiated using self-invented intellectual property. I'm not going to go into too much detail, but I'd like to give you just a little flavor of the potential programs and the achievements at AMF.

One project was development of an advanced cochlear implant system that does not just provide cues to enable communication, but truly restores quality hearing to severely and profoundly deaf people. Today, we are even seeing these people enjoy music, with the ability to recognize hundreds of percepts—in one patient, 1,200 percepts. This had never been done before. This product is now licensed to a subsidiary of Boston Scientific and enjoys sales of close to $100 million, growing at more than 30 percent per year—almost 60 percent projected for next year. Another product is a long-lived implantable glucose sensor, which is being combined with an insulin pump at Medtronic to create an artificial pancreas.

AMF also developed this tiny, single-channel neurostimulator called the "Bion." This is a fully powered system, even with bidirectional telemetry. It's in clinical trials now and is designed to eliminate migraine headaches, urinary incontinence, sleep apnea, erectile dysfunction, and soon many more applications.

The Bion system is being further developed so that these tiny devices will be able to communicate with each other and with a sensor and a control unit. These versions will be used to restore function to arms and legs that are paralyzed by stroke, spinal cord injury or others diseases. These systems will operate without the wires that have limited the success of systems in the past. And AMF has done so much more. Some of its contributions are in technical support of other companies. For example, AMF has helped Second Sight in developing a visual prosthesis. You're going to hear a little bit more about it in one of these other programs this afternoon from Dr. Rizzo from the Retinal Implant Project at the Boston VA Medical Center, and you heard this morning from Secretary Principi about the interest of the Government in this kind of a program. Work in visual prostheses is also going on at the

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Naval Research Laboratory. This is a very exciting future program. Second Sight has been developing the visual prosthesis and has already implanted its first generation in six human patients. The results have truly exceeded our expectations, so much so that Second Sight will actually commercialize its second generation system, which is expected to begin clinical trials in mid-2005. So, in just a few months, we're going to be seeing patients with visual systems we think will restore a reasonable function of sight.

We've learned a great deal from these early implants, and we believe this system will provide quite usable sight, first to people blinded by retinitis pigmentosa, and perhaps later for those impaired by macular degeneration.

There's so much more. Indeed, AMF has already created a number of major products. As the result, AMF has already earned royalties and license agreements that will turn over $200 million to its endowment.

The institute model is being fashioned to build on the success at AMF. The first of these institutes was established at the University of Southern California (USC). It's currently pursuing eight medical device projects that appear to be very promising. Because of the early success at AMI/USC, I've already increased its endowent to $162 million, and I may increase it still more. The association has been very successful also for USC in a number of ways because, for example, it has helped in recruiting prestigious faculty and promising students. It's also played a significant role in attracting three major Government-sponsored centers of excellence in the last couple of years.

My current challenge is to determine which additional universities ought to receive AMIs. I've already selected Johns Hopkins, and I have a list of 18 other prime prospects in the United States.

Because of limitations on my time, I'm forming a small search committee that will evaluate the potential partners and bring to me a selection of about 15 potentially suitable universities. With this search committee, I will make final selections and move to establish affiliation agreements, probably for a total of about 12 institutes.

I can't really say that all these AMIs will meet the challenge of getting life-changing inventions to people who need them. But it is one approach that I believe could be significant, one that could make a difference.

This may be one way that I believe we can help improve the transfer process. It's my hope and my way of repaying to my country and society for what they've given to me.

We need to be very constructive. We've got to start with a clean sheet of paper because what's happened so far has had very limited success. We need to find ways of translating the intellectual property to the clinic and to the commercial markets.

I am trying to do it in one way, and I'm sure there are other people out there trying to find other solutions to the problem. If we all are lucky and work hard, we'll make a difference.

I'd like to take a couple of moments to talk about some other impediments to the goal of getting valuable products to market. First, our Government expends considerable money supporting research at our academic institutions. These investments are generally quite important, and they sponsor really vital research.

Yet there seems to be a reluctance within the Government to support such developments in young companies. There are a few programs that are available to companies, and they are important but with relatively small funding. With the added obstacle of financing that has been affected because of the business scandals of these last few years, it's very, very difficult for young companies to raise money. Venture capitalists today seem to prefer more advanced programs, and so the young companies really need help. We need to find ways of doing this. A few arrangements are available where the government can provide limited support, but it's only modest. We need a lot more

if we are to efficiently bring some of the life-saving or life-improving products to those people who can benefit from them.

Another problem we have is our regulatory process, which must be redefined to better identify the risk/benefit ratios. Some progress has been made in the past couple of years, but not nearly enough. I realize that it's difficult for a Government employee to assume even minimal risk. He or she does not think as an entrepreneur. Much more could be done to make the process quicker, more effective, and far less costly. As one example, how can we justify denying experimental therapies to hopelessly terminal patients? Yes, there's been an attempt to find a way, but it truly doesn't work.

We apparently need legislation to give complete freedom to a patient judged by maybe two or three physicians to be terminal. Such a patient should be entitled to choose any therapy he or she wants without any impact on a company that supplies experimental products. If the patient is terminal and sent home to die, why should he or she be restricted? Even if the therapy is potentially ineffective or even unsafe; after all, dying is not safe. Is the person really worse off trying alternative treatments? Even an unsafe therapy may be palliative.

Other improvements to the regulatory process need to be implemented to accelerate availability of promising new therapies. One possibility might be to carry out some of the efficacy trials as part of a limited marketing program, with postmarket surveillance. Another need, I might say, is to increase the salaries of FDA staff and all Government, for that matter, to competitive levels so that our Government will be able to hire adequate staff. Of course, this is difficult, especially in these days of huge budget deficits. Yet we've got to find a way of getting the right kind of people into Government because that's what we need if we're going to make this process effective. Thank you.

Bio:

Alfred E. Mann is the Chairman of the Board of Trustees of the Alfred Mann Foundation, founded in 1985, and the Alfred Mann Institute for Biomedical Engineering at the University of Southern California. The Foundation and the Institute are nonprofit research organizations devoted to development of advanced medical products in a variety of fields. Mr. Mann is Chairman of Advanced Bionics® Corporation; Second Sight, LLC; MannKind Corporation, Quallion, LLC; and Chairman Emeritus of Pacesetter® System, Inc., and MiniMed Inc., all companies founded by Mr. Mann. Mr. Mann formally retired as CEO of Pacesetter in 1992 but continued to serve as Chairman Emeritus. Pacesetter System, Inc., now a St. Jude Medical company, develops, manufactures, and distributes cardiac pacemakers and implantable defibrillators worldwide. Mr. Mann had also founded a business in microinfusion pumps and glucose sensors used for delivering controlled profiles of insulin to treat diabetes. Prior to his involvement in the medical device industry, Mr. Mann had also been founder and was President of Spectrolab of Sylmar, California. Before founding Spectrolab, Mr. Mann was a group supervisor at Technicolor Corporation, where he directed research and development in the fields of instrumentation, radiation damage, optical physics, multilayer thin-film vacuum deposition, and digital and analog computer analysis. In addition to his business activities, Mr. Mann has contributed significantly to numerous technical advances in medical devices, photovoltaic power conversion, illumination, radiometry, vacuum physics, thin-film optics, and advanced methods of mathematical analysis. He holds numerous patents, with a number pending, and has authored a number of scientific papers. He is a graduate of the University of California at Los Angeles with extensive graduate work in nuclear and mathematical physics. Under Textron's sponsorship, Mr. Mann also attended an Advanced Management Program at the Harvard Business School.